DEC 9 2005

K053201

APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY

(per 21 CFR 807.92)

CL1000 IR Laser System

I. Applicant:

Curae'Lase Inc.
2315 Hwy 701 South
Loris, SC 29569
843 – 455-7020

Date Prepared: November 15, 2005

II. Device Name

Proprietary Name:	CL1000 IR Laser System
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The CL1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

IV. Predicate Devices

Predicate devices to the CL1000 IR Laser System include, but not limited to, the Meditech International Inc BioFlex Professional Therapy System (K023621), the Dynatronics Solaris D890 Therapy Probe (K040729), Light Force Therapy, Inc. Super Nova and Acubeam Systems (K001179), Medical Laser Therapeutics, LP MLT-1000 IR Laser System (K033986) and the Spectrum Laser & Technologies, Inc. Neurolase Series (K032787). These devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification process.

V. Description of the Device

The CL1000 IR Laser System is a non-invasive, easy to use, hand-held therapeutic device providing continuous heat therapy. The System is comprised of a Control Unit that houses the electronics and controls the handheld treatment probe, which delivers infrared energy.

VI. Summary of the technical characteristics of the CL1000 IR Laser System to the referenced predicate devices

The CL1000 IR Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VII. Testing

Testing of the CL1000 IR Laser System will include functional performance testing and electrical safety testing in accordance with all applicable standards for this type medical device.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the CL1000 IR Laser System has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Federal Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Curae'Lase Inc.
C/O M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services
12101- A Cullen Blvd.
Houston, Texas 77047-2951

Re: K053201
Trade/Device Name: CL1000 IR Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamps
Regulatory Class: Class II
Product Code: ILY
Dated: November 15, 2005
Received: November 23, 2005

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX C

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): ~~Pending~~ K053201

Device Name:

Curae'Lase Inc. CL1000 IR Laser System

Indications for Use:

The Cl1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Prescription Use: X **AND/OR** **Over the Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K053201